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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/450,073	11/29/1999	Orest W. Blaschuk	100086.405C2	7100

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EXAMINER
GUPTA, ANISH

ART UNIT	PAPER NUMBER
1653	11

DATE MAILED: 08/13/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/450,073	Applicant(s) BLASCHUK ET AL.	
	Examiner Anish Gupta	Art Unit 1653	

-- Th MAILING DATE of this communication appears on the cover she t with the correspondenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) *1,6,26 and 31* is/are allowed.

6)☐ Claim(s) *2-5,7-25,27-30,32 and 33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *9 & 10* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Prosecution on the merits of this application is reopened on claims 2-5, 7-25, 27-30, 32-33 considered unpatentable for the reasons indicated below:

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 2-5, 7-15, 17-18, 20-25, 27-30, 32-33 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The MPEP states that the purpose of the written description requirement is to ensure that the inventor had possession, as of the filing date of the application relied on, of the specific subject matter later claimed by him. The courts have stated:

"To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966." Regents of the University of California v. Eli Lilly & Co., 43 USPQ2d 1398.

Further, for a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In Regents of the University of California v. Eli Lilly & Co., the court stated:

"A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials. Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606; In re Smythe, 480 F.2d 1376, 1383, 178 USPQ 279, 284-85 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus. . . ."). Regents of the University of California v. Eli Lilly & Co., 43 USPQ2d 1398.

The claims of the instant application are drawn to a method of enhancing delivery of a drug to a tumor in a mammal by administering a cell adhesion modulating agent and a drug, wherein the modulating agent comprises an antibody or fragment thereof that specifically binds to an occluding cell adhesion recognition sequence. (See claim 28) This generic statement of the modulating agent, without more, is not an adequate written description of the genus because there is no distinguishing feature except function. That is, the generic statement does not adequately define the species that fall within the definition since there is no structural feature commonly possessed by the member of the genus that distinguishes them from others. Accordingly one of ordinary skill in the art cannot readily visualize or recognize the identity of the members of the genus. A genus can be described by means of reciting a representative number of species that fall within the scope of the genus or of a structural features, which constitutes a substantial portion of the genus, that are common to the members of the genus. In the instant case, the specification fails to adequately describe a structural feature common to the genus of the modulating agent. Nor does the

specification provide a reasonable number of examples that would reasonably convey to one of ordinary skill in the art the members of the genus. The only description provided in the specification, with respect to specific compounds, all contain a LYHY motief. The specification recites peptides that are fragments of the sequence QYLYHYCVVD to exemplify the broad generic. The disclosure fails to teach a single species that is not a variant of this sequence or a sequence that does not contain the LYHY motief. The disclosure of a handful of peptides does not constitute a representative number of examples for the broad genus since one of ordinary skill in the art cannot readily visualize or recognize the identity of the members of the genus. It has been held by the courts that a small number of examples do not constitute a representation of a broad genus. Gostelli, 872 F.2d at 1012, 10 USPQ2d at 1618 (determining that the disclosure of two chemical compounds within a subgenus did not describe that subgenus); In re Grimme, 274 F.2d 949, 952, 124 USPQ 499, 501 (CCPA 1960) (" [I]t has been consistently held that the naming of one member of such a group is not, in itself, a proper basis for a claim to the entire group. However, it may not be necessary to enumerate a plurality of species if a genus is sufficiently identified in an application by 'other appropriate language.' ") (citations omitted). The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See In re Wilder, 736 F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, the examples provided in the specification cannot constitute written description to any modulating agent as encompassed by

the claims. Accordingly, it is deemed that the specification fails to provide adequate written description for the genus of the claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 16-25 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in In re Wands, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

(1) The nature of the invention:

The invention is drawn to peptides that enhance delivery of a drug to a cell. The peptides binds to the occluding cell adhesion recognition sequence and increases permeability to the cells.

(2) The state of the prior art

The art recognizes the linkage between occluding and the ability to impair tight junction sealing. The art has recognized of small peptides of the external loop of Occluding impair tight junction resealing and thus allowing for increased permeability. For example, Vieira et al. teach that the peptides SNYYGSGLSY and SNYYGSGLS impaired junction resealing when the peptides were included in the apical bathing fluid (see abstract). However, the art has not recognized the ability of peptides recognizing Occluding to inhibit tumor growth or treat any type of cancer.

(3) The relative skill of those in the art

The relative skill of the those in the art is high.

(4) The predictability or unpredictability of the art

Given that the art has not recognized the ability of peptides recognizing Occluding to treat cancer, it would be unpredictibiltiy to determine the ability of a peptide recognizing Occluding to treat cancer. Further, as with most invivo treatment methodologies, it is highly unpredictable to determine the effect of a given compound on a biological system.

(5) The breadth of the claims

The claims are drawn to a method of treating cancer by the administration of a peptide comprising the sequence LYHY or administering a cell adhesion modulating agent. The claims do not recite the administration of this peptide or agent with another drug that has antitumor activity.

(6) The amount of direction or guidance presented and (7) The presence or absence of working examples

The specification does provide guidance any guidance as to the ability of the LYHY peptide or cell adhesion modulating agents to treat cancer. The specification only discloses that such agents enhance the permeability of a cell there by allowing increased access to known drugs that have anti-tumor or anti-cancer activity. In every context recited in the specification, the peptide or agent is administered with either another therapeutic agent or the other therapeutic agent is administered after the peptide or modulating agents have been administered. The specification is void of any guidance that would clearly indicate that a peptide with the motif LYHY or a cell adhesion modulating agent was solely responsible for the treatment of cancer. Applicants specification is quite similar to disclosure of *Ex parte Sudilovsky*, where it was held that the disclosure was non-enabling since:

> "['the strong feeling one gets from reading the entire specification is that either appellant did not have possession of the details of a single operative process or, if he did, he chose not to divulge them.'"

Ex parte Sudilovsky, 21 U.S.P.Q2d 1702 (BPAI 1991). Similarly, the disclosure of the instant application, with regard to the peptides and treatment of cancer, is confined to a broad allegations and suggestions without substantiating working examples. Although working examples are not necessary in the specification, lack of a working example, however, is a factor to be considered, especially in a case involving an unpredictable and undeveloped art. When a patent applicant

chooses to forego exemplification and bases utility on broad terminology and general allegations, he runs the risk that unless one with ordinary skill in the art would accept the allegations as obviously valid and correct, the examiner may, properly, ask for evidence to substantiate them. *In re Novak*, 306 F.2d 924, 134 USPQ 335 (CCPA 1962) 4; *In re Fouche*, 439 F.2d 1237, 169 USPQ 429 (CCPA 1971).

(8) The quantity of experimentation necessary

Since, the art indicates a level of unpredictability in determining activity of a peptide and the disclosure does not provide any guidance for the treatment of cancer with a peptide containing LYHY or a cell adhesion modulating agent, one would be burdened with undue experimentation to practice the claimed invention for the reasons stated above.

Information Disclosure Statement

The reference of Jaeger et al. has not been considered since the incorrect reference was provided.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anish Gupta whose telephone number is (703) 308-4001. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can normally be reached on (703)308-2923. The fax phone number of this group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Anish Gupta

August 12, 2002

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